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ABSTRACT:

1 367 846

PATENT SPECIFICATION

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(54) LOW REFRACTIVE INDEX CONTACT LENSES

(71) We, E. I. DU PONT DE NEMOURS AND COMPANY, a Corporation organised and existing under the laws of the State of Delaware, United States of America, of Wilmington, State of Delaware, United States of America, do hereby declare the invention, for which we pray that a patent may be granted to us, and the method by which it is to be performed, to be particularly described in and by the following statement:

This invention relates to particular novel transparent soft contact lenses for correcting vision deficiencies of the human eye.

Contact lenses are of two general types, scleral and corneal. Lenses of the scleral type cover a substantial area of the eye, during use, thereby sealing off circulation of tears and the atmosphere. This causes partial asphyxiation which affects the metabolism and vision of the eye. The more recently developed corneal lenses, because of their relatively smaller size and lighter weight, may cause less irritation to the cornea, and have achieved greater acceptance. However, the "break in" period necessary to accustom the cornea of the wearer to support a corneal lens, while varying from person to person, depending upon the individual's sensitivity of the cornea, usually extends over a considerable period of time. Some persons have found contact lenses to be intolerable because of the eye irritation resulting during and after any extended period of continuous wear.

Contact lenses of both the corneal and scleral types have been commonly constructed of poly(methyl methacrylate) (PMMA) which has a Knoop hardness of about 20-22. When a PMMA corneal contact lens is introduced for the first time into the eye of a patient, the sensation is that of a foreign body being

introduced. A fraction of those who try PMMA lenses become adapted after a break-in period so that they can successfully wear the lenses with little or no discomfort. A larger fraction of the individuals who attempt to wear PMMA lenses never become wearers because they cannot adapt to the lenses for reasons of discomfort, irritation, excessive tearing, and the like. However, even those individuals who adapt successfully to PMMA lenses and do not have discomfort suffer an awareness of the lens in the eye. Clearly then, there is a need for more comfortable contact lenses, particularly lenses affording instant comfort to beginning wearers.

Attempts have been made to design contact lenses for comfort and for proper fluid circulation. U.S. Patent 3,542,461 discloses the advantage of constructing polymers having a refractive index of tears, i.e., about 1.336, and a Knopp hardness greater than 2.

In recent years there has been increasing attention given to so-called soft lenses, particularly those constructed from hydrogels and from silicones, e.g., U.S. Patent Nos. 3,228,741 and 3,220,960. These lenses are characterized by outstanding comfort which is immediately apparent to the wearer. This is a very important feature, particularly with new wearers who would thereby be encouraged in their efforts to wear contact lenses. However, the hydrogel and silicone lenses have some serious drawbacks which make it unlikely that they will ever achieve general acceptance. These drawbacks include poor or variable visual acuity resulting from difficulties in the manufacture of the lenses and, in the case of the hydrogel lens, variable water absorption, tendency to absorb foreign substances, including tobacco smoke, bacteria, fluorescein, wetting solutions, mascara and

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- necessity for daily sterilization. In addition, the hydrogel and silicone lenses are weak and subject to damage by tearing and breaking.
- The present invention comprises a wettable scleral or corneal contact lens constructed from at least one fluorine-containing polymer, said lens having an optical zone, a refractive index of 1.30 to 1.40, a Knoop hardness of less than 2 at loadings up to 25 grams and a Shore Durometer "A" hardness of less than 100. The optical zone of the novel lens is the molded or optically ground portion of the lens designed to lie over the surface of the eye in a position to correct the vision defect.
- The softness of the lenses, as evidenced by the low Knoop and Shore Durometer values, ensures excellent comfort to the wearer. In fact, comfort is equal to or greater than that observed with hydrogel and silicone lenses. At the same time the lenses are tough and strong enough to maintain constant visual acuity and to resist damage by tearing, breakage, abrasion or irreversible elastic deformation. Furthermore, the inert nature of the fluorine-containing polymer(s) ensures that the lenses will not absorb bacteria, lens-wetting and sterilizing solutions, fluorescein, tobacco smoke, mascara and other deleterious materials.
- The lens described herein is also characterized by a refractive index of 1.30 to 1.40. It is preferred that the refractive index be close to that of tears, which is 1.336.
- Because of the low refractive index of the polymers and lenses of this invention, the lenses may be modified to obtain benefits not possible with lenses of higher refractive indices. For example, the posterior lens surface can be spherical or aspherical over part or all of the surface; or it may have one or more peripheral curves to improve fit and comfort; or it may be textured, patterned or channeled to improve the flow of oxygen and tears to the eye, all without adversely affecting visual acuity.
- The posterior surface of the lens may have patterns cut or molded therein but such patterns are not necessary.
- The pattern will be one of channels, grooves, chamfers, striations, etc., hereafter referred to embracively as "channels". The channels are cut or molded into the posterior surface but not through to the anterior surface, essentially parallel to the surface of the eye and extending into the optical zone. It is contemplated that the largest dimension of these channels can extend into the optical zone and can be as long as or longer than the diameter of the optical zone.
- Hereafter, unless otherwise indicated by the context in which used, the word "polymer" such as in "fluorine-containing polymer", is meant to include homopolymers, copolymers (including terpolymers), and combinations or blends of polymers derived solely from fluoromonomers or from fluoromonomers together with nonfluorinated monomers.
- Preferred features of the invention will now be described, by way of example, with reference to the accompanying drawings, in which:
- Figure 1 is a vertical cross-sectional view of a portion of a human eye to which there has been applied a corneal contact lens that forms one embodiment of this invention. Figure 2 is a vertical cross-sectional view of a portion of a human eye to which a scleral contact lens has been applied. Figure 3 is the same view as Figure 2 showing channels on the posterior side of the lens.
- Figures 4 to 15 are posterior views of contact lenses of generally concavo-convex cross section to which various patterns have been added. For example, the channels in Figure 4 are arranged in a pinwheel pattern; in Figure 5, a spoked wheel pattern; in Figure 6, a square waffle pattern; in Figure 7, a wheel pattern; in Figure 8, a cross pattern. Figures 9 to 15 show other representative patterns.
- In Figures 1 to 15, the lens is represented by numeral 1 and the channels by numeral 7. In the depiction of the eye in Figures 1, 2 and 3, the cornea is 2, the sclera is 3, the limbus is 4, the pupil is 5, and the iris is 6. It should be noted that between the eye and the lens is a tear layer that is not shown in the drawings.
- Figures 16, 17 and 18 are posterior views of three typically designed bifocal lenses. The Figures show the lenses with patterns although as should be understood from the teaching herein, patterns are not necessary but are preferred. In these Figures, numeral 10 represents the portion of the lens used for seeing in the distance, numeral 11 represents the portion used for seeing near and numeral 12 represents the demarcation between the two portions of the lens. Other variations of the bifocal lens are possible though not specifically depicted as other pattern arrangements are possible though not depicted.
- Some of the fluorine-containing polymers useful herein are listed in the table below, together with refractive indices, Knoop hardness and Shore Durometer "A" hardness data. The polymer and their abbreviations are:
- | | | |
|-----------------|---|---------------------|
| HFA | = | hexafluoroacetone |
| EO | = | ethylene oxide |
| PO | = | propylene oxide |
| TFE | = | tetrafluoroethylene |
| VF | = | vinyl fluoride |
| VF ₂ | = | vinylidene fluoride |

| | | |
|---|--------|---|
| | HFP | = hexafluoropropylene |
| | HBVE | = 4-hydroxybutyl vinyl ether |
| | PSEPVE | = perfluoro[2(2-fluorosulfonylethoxy)propyl vinyl ether] |
| 5 | P,MVE | = perfluoro (methyl vinyl ether) |
| | P,PVE | = perfluoro (propyl vinyl ether) |
| | TFP | = 3,3,3-trifluoropropylene |
| | P | = propylene |

TABLE

| No. | Polymer | Composition (mol ratio) | Hardness | | |
|-----|--------------------------------|----------------------------|------------------|-------------------------------------|-----------------------------------|
| | | | $n_{D^25}^{(1)}$ | Knoop ⁽²⁾ (Load, g) | Shore ⁽³⁾ Durometer |
| 1 | HFA/PO | 1:1 | 1.3650 | 0.015 (1) | 25 |
| 2 | HFA/PO/epoxy vinyl cyclohexane | 48.5:48.5:1 | 1.3700 | Too soft to measure | 15 |
| 3 | HFA/EO/PO | 4:1:3 | 1.3676 | 0.021 (1) | 29 |
| 4 | HFA/EO/PO | 3:2:1 | 1.3630 | 1.23 (25) | 97 |
| 5 | HFA/EO/PO | 4:3:1 | 1.3600 | 1.4 (25) | — |
| 6 | HFA/BO/PO | 2:2:1 | 1.3680 | — | — |
| 7 | HFA/VF | — | 1.3700 | 0.59 (10) | 64 |
| 8 | HFA/VF ₂ | 37:63 | 1.3500 | 0.024 (1) | 9 |
| 9 | HFA/VF ₂ | 21.5:78.5 | 1.3850 | 0.569 (25) | 87 |
| 10 | HFA/VF ₂ | 24:76 | ca. 1.3800 | 0.236 (10) | 45 |
| 11 | TFE/P(SRPVE) | 8.28 | 1.3400 | 0.38 (10) | 81 |
| 12 | TFE/P,MVE | 64:36 | 1.3270 | Recovered too quickly to measure | 57 |
| 13 | TFE/P,MVE | 70:30 | 1.3300 | Recovered too quickly to measure | 65 |
| 14 | TFE/P,MVE/VF ₂ | 12:30:58 | 1.3700 | 0.24 (10) | 48 |
| 15 | VF ₂ /HFP | 60:40 (wt. ratio) | 1.3713 | 0.90 (25) | 36 |
| 16 | VF ₂ /HFP/TFE | 45:30:25 (wt. ratio) | 1.3617 | 0.021 (1) | 43 |
| 17 | HBVE/TFE | 1:1 | 1.3500 | 0.015 (1) | — |

TABLE (continued)

| No. | Polymer | Composition (mol ratio) | $n_{D^{25}}^{(1)}$ | Hardness | |
|-----|-------------|----------------------------|--------------------|-----------------------------------|-----------------------------------|
| | | | | Knoop ⁽²⁾ (Load, g) | Shore ⁽³⁾ Durometer |
| 18 | | $n=2$ | 1.3730 | 1.2 (25) | — |
| 19 | | $n=2$ and 3 1:1 | 1.3720 | 1.7 (25) | — |
| 20 | | $n=2$ and 3 3:7 | 1.3720 | 1.7 (25) | — |
| 21 | | $n=2$ and 3 7:3 | 1.3720 | 1.4 (25) | — |
| 22 | Polyfluoraf | Homo-polymer | 1.3285 | Too soft to measure | — |
| 23 | TFP | Homo-polymer | 1.3580 | — | — |
| 24 | TFE.P | 1:1 | 1.3843 | — | 23 |

Notes:

- (1) Refractive Index, measured by standard techniques on an Abbe Refractometer.
- (2) Conventional measurement of the hardness of polymer sheets and films. Values were determined according to ASTM D1474—68 on a Tukon Micro-Hardness Tester, Model MO, employing varying loads to insure measurable indentations.
- (3) Conventional hardness measurement employing a Type A Shore Durometer in accordance with ASTM D2240—68. Some of the reported values represent an average of more than one measurement.

Additional useful polymers, copolymers and compositions not listed in the Table are:

- | | | | | |
|----|--|--|--|----|
| 25 | vinyldene fluoride/perfluoro (methyl vinyl ether) | fluoroburyl acrylate) | poly(α,ω -trihydroperfluoroalkyl methacrylates), e.g., poly(α,ω -trihydroperfluoropentyl methacrylate) | 10 |
| 5 | tetrafluoroethylene/methyl vinyl ether | tetrafluoroethylene/perfluoro (propyl vinyl ether) | 29 | |
| 26 | poly(α,ω -tetrafluoroethylene / dihydroperfluoroalkyl acrylates), e.g. poly(α,ω -dihydroper- | tetrafluoroethylene / vinyl ether | 30 | |

| | | | |
|----|----|---|---|
| | | | 3,342,277, polymers No. 7, 8, 9, 10 and 24; |
| | | 31 3,3,3 - trifluoropropylene/tertafluoro- ethylene (1:1 molar copolymer) | 3,282,875, polymer No. 11; |
| | | 32 3,3,3 - trifluoropropylene/vinyl fluoride (36/64 wt. %) | 3,132,123, polymers No. 12, 13, 26 50 and 30; |
| 5 | 33 | tetrafluoroethylene/perfluoro (methyl vinyl ether) blended with polytetra- fluoroethylene | 3,235,537, polymer No. 14; 3,051,677, polymer No. 15; |
| | 34 | tetrafluoroethylene/perfluoro (methyl vinyl ether) plasticized with poly(hexa- fluoropropylene oxide) oil | 2,968,649, polymer No. 16; 3,282,905, polymer Nos. 18, 19, 29 55 and 21; |
| 10 | 35 | low refractive index fluoropolymer blends with silicone rubbers | 2,549,589, polymer No. 23; 2,468,664, polymers Nos. 25 and 27; |
| | 36 | low refractive index fluoropolymer, such as polyperfluoro - 2 - methylene- 4 - methyl - 1,3 - dioxolane (PMD), of Knoop hardness of 2 or more plasti- cized to a hardness value of less than 2 with low refractive index fluorine- containing oils such as (a) poly-(per- fluoropropylene oxide) (Krytox®) and (b) linear oligomers of hexafluoro- propylene | 3,467,635, polymer No. 25; 3,429,845, polymer No. 17; 2,628,958, polymer No. 29; 2,484,530, polymer Nos. 32 and 33; and |
| 15 | 37 | blends or other combinations of any of the above polymers as numbered or as combined in any other manner to produce a lens having the desired physical properties described herein, and | 3,484,503, polymer No. 34. |
| 20 | 38 | blends of the polymers described above | Lens Permeability 55 |
| | 30 | with finely divided transparent inert, water insoluble fillers. | Permeability of the novel lenses to O ₂ and CO ₂ has been found to be a valuable property. Good permeability in the novel lenses is a desirable health factor in that O ₂ can permeate through the lens to nourish the eye and CO ₂ metabolic waste can permeate through the lens and away from the eye. The lens perme- ability is an important asset even though pat- terns can be employed to aid tear flow. Oxygen and carbon dioxide permeabilities of about 500 Centibarrers or more, at 1 PSIG, are considered very desirable. Permeabilities somewhat below about 500 Centibarrers may, however, also give benefit. It should, of course, be understood in this regard that the further the permeability ranges below about 500 Centibarrers, the more impermeable the lenses and the less the beneficial effect derived from lens permeability. 70 |
| | | | 80 |
| 35 | | Those skilled in the art, with the aid of the teaching of this invention, will be able to prepare the polymers used herein without diffi- culty. As an additional aid in preparing the polymers from which the novel soft contact lenses are fabricated, attention is directed to the following co-assigned U.S. Patents wherein are taught the preparative details, etc., concerning various of the polymers dis- closed herein. The particular polymers are noted after the parent number, by number designations corresponding to those set out above. | 75 |
| 40 | | 45 U.S. 3,316,216, polymers No. 1, 2, 3, 4, 5 and 6; | The novel contact lenses are significantly more permeable to oxygen and carbon di- oxide than various art polymers represented by, for example, the well-known contact lens polymer, poly(methyl methacrylate), PMMA. The following comparisons show the increased oxygen permeabilities of some of the poly- mers used in the novel contact lenses: 85 |
| | | | 90 |

Those skilled in the art, with the aid of the teaching of this invention, will be able to prepare the polymers used herein without difficulty. As an additional aid in preparing the polymers from which the novel soft contact lenses are fabricated, attention is directed to the following co-assigned U.S. Patents wherein are taught the preparative details, etc., concerning various of the polymers disclosed herein. The particular polymers are noted after the parent number, by number designations corresponding to those set out above.

45 U.S. 3,316,216, polymers No. 1, 2, 3, 4, 5 and 6;

O_2 Permeability Centibarriers

| Polymer | O_2 Permeability Centibarriers | | |
|--|----------------------------------|---------------------|----------|
| | 1 Psig | Pressure 15 Psig | 100 Psig |
| PMMA | — | — | 13* |
| TFE/PtMVE | 1,190 | 1,202 | — |
| TFE/PtMVE | 2,740 | 1,150 | — |
| plasticized with 10% poly(perfluoropropylene oxide) oils | | | |
| HFA/EO/PO (2:1:1) | — | 1,462 | — |
| Polyfluoral | — | 2,585 | — |

* Permeability is nil at lower pressures.

Bifocal Lenses

The soft, tough plastic lenses of this invention can be constructed in a variety of ways so as to provide for the refractive and physical requirements of different individuals. Among the several types of lenses are the soft, tough single vision lenses having symmetrical spherical anterior and posterior curves. This type of lens meets the needs of the majority of contact lens patients. Other types of lenses falling within the scope of this invention include: (1) soft, tough toric lenses having non-spherical anterior and/or posterior curves; and (2) soft, tough bifocal lenses which are designed to provide near and far vision for individuals whose eyes have lost accommodative power.

Among the several types of bifocal lenses which may be constructed according to the teachings of this invention are (a) the peripheral near-segment bifocal lenses, Fig. 16, in which distant vision is provided by the curves on the central segment and near vision by the curves on the peripheral segment; (b) upper and lower segment bifocal lenses, Figs. 17 and 18, in which distant vision is provided by the curves on the upper segment and near vision by the curves on the lower segment. Other types of lenses considered to be within the scope of this invention are prism ballast lenses, truncated lenses and lenticular lenses.

Construction of Lenses

Two general methods in use for manufacture of contact lenses constructed of poly(methyl methacrylate) or other hard material are as follows: (1) cutting of lenses from blanks on a radiusing lathe, followed by polishing and edging with a grinding or cutting device, and (2) compression molding of

the plastic with precision molds of glass or steel, followed by edging by cutting or grinding.

The lenses of this invention, because of their soft, tough nature, are preferably fashioned by compression molding (2nd method), using precision molds constructed of suitable materials such as glass, stainless steel, carbon steel, carbides such as WC and TiC; brass, Ni- and Cr-plated steel or brass; and the like. By employing suitably constructed male and female mold forces, lenses can be molded which have anterior and posterior surfaces with the desired curvatures and degree of smoothness (polish) and which also have adequately tapered and rounded edges, so that the molding operation produces a finished lens, ready for wear. Or if desired, the mold forces can be constructed so as to produce a so-called semi-finished lens, that is, one with proper anterior and posterior curves but which has not been edged. The lens is subsequently edged to provide a comfortable fit.

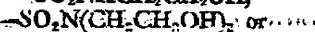
Wettability is an essential requirement for corneal lenses especially, in order for them to provide comfort and good visual acuity. Certain of the polymers which may be used in constructing the lenses of this invention are inherently wettable by tears. An example of this type is HFA/VF₂ copolymer. In the case of other polymers, wettability is achieved by altering the hydrophobic surface to a hydrophilic surface by any of several methods that will readily occur to those skilled in the art.

One generally applicable method involves subjecting the lenses to the action of a glow discharge at a low pressure of, say 1 mm of Hg for a limited time of, say, 15 seconds. The lens is then wettable when placed in

water. In a variation of this method, a vinyl monomer containing a hydrophilic group, e.g., acrylic acid is admitted to the lens, in either liquid or vapor form, after its exposure to the discharge but before exposure to air. This results in formation of a wettable hydrophilic film on the lens.

Another method for imparting wettability which is widely applicable to the polymers of this invention consists in etching the surface of the lens with sodium or other alkali metal as a solution in anhydrous NH₃ or as a complex with naphthalene in solution or in suspension in tetrahydrofuran or other inert ethers, followed by exposure to water to destroy excess alkali metal. In some instances the treatment leaves a brown discoloration on the surface which is removed, frequently with enhancement of wetting, by exposure of the lens to warm commercial household bleach solution for several minutes. The method is particularly applicable to one of the preferred polymers, TFE/P,MVE.

Another preferred polymer, a TFE/PSEPVF copolymer, can be rendered wettable by converting hydrophobic surface sulfonyl fluoride ($\text{--SO}_2\text{F}$) groups to more hydrophilic groups. For example, wettability is imparted by brief immersion of lenses of this polymer in hot ethanolamine, diethanolamine, or aqueous 5% sodium hydroxide solution, and forming the groups



respectively, on the surface.

The following Examples are meant to illustrate but not to limit the invention.

EXAMPLE 1.

A quantity of TFE/P,MVE copolymer mol ratio 64:36 was placed in a conventionally prepared steel lens mold previously heated to 200°C, allowed to stand for 2 minutes, and a total force of 100 lbs then applied to the mold. The sample was maintained at 200°C and 100 lbs pressure for 5 minutes, and then quickly cooled to room temperature while the pressure was maintained.

The mold was then opened and the lens then removed. The lens was transparent, colorless, soft, and flexible, yet tough and elastic, with well-feathered, smooth edges. The edge of the lens was good enough so that it could be worn comfortably without further modification. It weighed 53.5 mg and had a diameter of 12 mm and a central thickness of 0.157 mm.

The lens was made wettable with water by subjecting it to a corona discharge at reduced pressure. The wetted lens was then placed on the right eye of a test subject who at the same time was wearing a conventional PMMA

corneal lens as a control on his left eye. The lens centered perfectly and the subject reported the TFE/P,MVE lens to be more comfortable than the methacrylate lens and to be comparable in comfort with previously worn hydrogel contact lenses.

The subject experienced none of the "scratchiness", even when blinking, which he associated with PMMA corneal lenses.

EXAMPLE 2.

A quantity of TFE/P,MVE copolymer (mol ratio 64:36), in the form of a 4-layer sandwich of pieces cut from 25-mil film, was placed in a conventional steel lens mold heated to 200°C. After standing for 1 minute to attain temperature, the polymer was molded at 200°C and 125 lbs total mold pressure for 1 minute, and then cooled to room temperature under pressure, 12.9 mm; central thickness, 0.358 mm. The lens required edging, including removal of some flash on the periphery.

EXAMPLE 3.

A block of HFA/PO copolymer (mol ratio 1:1) in the steel lens mold of Example 2, heated to 55°C, allowed to stand for 2 minutes, and then molded for 1 minute at 55°C and 150 lbs. total pressure. The lens was cooled to room temperature while maintaining the pressure and then removed from the mold. The lens was very soft and brilliantly clear; weight, 40.9 mg; diameter, 10.8 mm; central thickness, 0.30 mm.

EXAMPLE 4.

A piece of 19-mil film of HFA/EA/PO (mol ratio 4:1:3) terpolymer was molded at 150°C and 150 lbs total pressure for 1 minute in the steel lens mold of Example 2, after allowing the polymer to temperature-equilibrate in the mold for 1 minute at 150°C. The lens was cooled to room temperature under pressure and removed from the mold. It weighed 39.0 mg and had a diameter of 10.7 mm and a central thickness of 0.305 mm.

EXAMPLE 5.

A quantity of HFA/EO/PO (mol ratio 2:1:1) terpolymer in the form of stacked pieces of cut film was placed in the steel lens mold of Example 2 and molded for 30 seconds at 135°C and 150 lbs total pressure. The lens was then cooled to room temperature under pressure and removed from the mold. The transparent, colorless lens weighed 41.7 mg and had a diameter of 10.5 mm, and a central thickness of 0.335 mm.

EXAMPLE 6.

A quantity of HFA/EA/PO (mol ratio 4:3:1) terpolymer in the form of stacked pieces of 10-mil film was placed in the pre-

heated steel lens mold of Example 2 and molded for 1 minute at 150°C and 100 lbs total pressure. The lens was then cooled to room temperature under pressure and removed from the mold. The lens was colorless, transparent and well-shaped but with rough edges; weight, 40.5 mg; diameter, 10.7 mm; central thickness, 0.328 mm.

EXAMPLE 7.

A piece of 55-mil film of TFE/P,MVE/VF₂ terpolymer (mol ratio 12:17:71) was placed in a preheated lens mold of Example 2 and molded for 1 minute at 220°C and 75 lbs total pressure. The lens was cooled to room temperature under pressure and removed from the mold. It was colorless, transparent, soft, rubbery, and tough with some peripheral flash; weight, 101.9 mg; diameter, 13.2 mm; central thickness, 0.256 mm.

EXAMPLE 8.

A quantity of TFE/PSEPVE copolymer (mol ratio 8:3:1) in the form of stacked pieces of 9-mil film was placed in the steel lens mold of Example 2, preheated to 250°C. After allowing 1 minute for temperature equilibration, the material was molded for 30 seconds at 250°C and 100 lbs total pressure. The mold was cooled to room temperature under pressure and the lens removed. The lens was transparent, soft, tough, and flexible; weight, 45.5 mg; diameter, 10.6 mm; central thickness, 0.262 mm.

EXAMPLE 9.

A quantity of TFE/HFP/VF₂ terpolymer (mol ratio 21.7:17.3:61) containing 57 wt % of VF₂ was preheated in the steel lens mold of Example 2 for 1 minute at 180°C and then subjected to the following molding cycle: 30 seconds at 180°C and 75 lbs pressure, followed by 30 seconds at 180°C and 150 lbs. The mold was cooled to room temperature under pressure and the lens removed. The well-formed lens weighed 49.9 mg and had a diameter of 11.2 mm, and a central thickness of 0.218 mm.

EXAMPLE 10.

A quantity of VF₂/HFP copolymer (mol ratio 78:22) was placed in the steel lens mold of Example 2, and heated to 180°C. After standing for 1 minute for temperature-equilibration, the sample was subjected to the following mold cycle: 30 seconds at 180°C and 75 lbs pressure followed by 30 seconds at 180°C and 100 lbs pressure. The mold was cooled under pressure and the lens removed. The well-formed lens was tough and rubbery; weight, 120.4 mg; diameter, 13.7 mm; central thickness, 0.348 mm.

EXAMPLE 11.

A quantity of VF₂/HFP copolymer (mol ratio 78:22), copolymerised in the presence of a small quantity of diethyl malonate as chain transfer agent, was placed in a pre-heated steel lens mold of Example 2, allowed to equilibrate for 1 minute at 120°C and subjected to the following molding conditions: 30 seconds at 120°C and 75 lbs pressure; 30 seconds at 120°C and 100 lbs pressure. The mold was cooled to room temperature under pressure and the lens removed. The lens weighed 158 mg and had a diameter of 13.5 mm and a central thickness of 0.376 mm.

EXAMPLE 12.

A quantity of TFE/P,MVE copolymer (mol ratio 64:36) in the form of stacked pieces of 25-mil sheet was placed in a conventional lens mold preheated to 280°C. The polymer was allowed to stand for 3 minutes for temperature equilibration and the pressure then raised to 75 lbs total pressure. Immediately thereafter, the lens was cooled rapidly to room temperature with maintenance of pressure. The well-formed lens weighed 121.8 mg and had a diameter, including flash, of 13.7 mm and a central thickness of 0.366 mm.

EXAMPLE 13.

A quantity of TFE/P,MVE (64/36 mol ratio) copolymer was placed in a conventional lens mold previously heated to 260°C, allowed to stand at 260° for 5 min. and a total force of 85 lbs then applied to the mold. The mold was then quickly cooled to room temperature while the pressure was maintained. The mold was opened and the lens removed. The well-formed lens had a central thickness of 0.34 mm and a total weight, including flash, of 132.8 mg. The flash was cut off and the lens was edged.

The lens was then made wettable with water by the procedure described in Example 1, and the wetted lens placed on the right eye of a patient. The patient's immediate reaction was that the lens was very comfortable and couldn't be felt except for a slight awareness on the lower region of the sclera. The lens remained comfortable during a wearing period of 1.5 hours. The patient did not experience flare or photophobia outdoors with the lens and edema was absent at the end of the wearing period. The patient's visual acuity with the lens was 20/15, when wearing a 2D auxiliary lens to compensate for a slight overcorrection in the lens. This indicated excellent optics for the lens.

EXAMPLE 14.

A block of TFE/P,MVE (64/36 mol ratio) copolymer was placed in a conventional lens

- 5 mold previously heated to 260°, allowed to stand for 5 min. at temperature and a total force of 50 lbs applied to the mold. The mold was then quickly cooled to room temperature while the pressure was maintained. The mold was opened and the lens removed. The lens weighed 126.2 mg and had a central thickness of 0.67 mm.
- 10 The subsequently edged lens weighed 98.5 mg; the diameter of the optic zone was 7.2 mm and the overall diameter was 12.6 mm. The lens was made wettable as described in Example 1. When worn by a patient having 20/400 uncorrected vision, the lens was very comfortable and provided visual acuity of 20/15.

EXAMPLE 15.

- 20 A block of TFE/P,MVE (64/36 mol ratio) copolymer was placed in a conventional lens mold previously heated to 260°C, allowed to stand for 5 min. at temperature and a total force of 50 lbs. then applied to the mold. The mold was then quickly cooled at room temperature while the pressure was maintained. The mold was opened and the lens removed. The well-formed lens had a central thickness of 0.59 mm and weighed 114.0 mg.
- 25 The subsequently edged lens weighed 81.2 mg; the optic zone had a diameter of 7.2 mm and the overall diameter was 11.9 mm. The lens was made wettable with water as described in Example 1 and worn by a patient. The visual acuity of said patient (having 20/400 uncorrected vision) was improved to 35 20/20 with novel lenses of this invention.

EXAMPLE 16.

- 40 A block of TFE/P,MVE (64/36 mol ratio) copolymer was placed in a conventional lens mold previously heated to 260°C, allowed to stand for 5 min. at temperature and a total force of 25 lbs. then applied to the mold. The mold was then quickly cooled to room temperature while the pressure was maintained. The mold was opened and the lens removed. The lens had a central thickness of 0.63 mm and weighed 89.2 mg including the flash.
- 45 The subsequently edged lens weighed 87.1 mg; the optic zone had a diameter of 7.2 mm and the overall diameter was 11.9 mm. The lens was made wettable with water as described in Example 1. The lens provided a patient with visual acuity of 20/25 while wearing an auxiliary ophthalmic lens of -0.75D to correct for a slight difference in 55 the power of the lens and the refractive requirement of the patient.

EXAMPLE 17.

- 60 A quantity of TFE/P,MVE copolymer plasticized with 10 wt % of a poly(perfluoropropylene oxide) oil, in the form of a stacked sandwich of pieces cut from 16-mil film, was placed in a conventional lens mold pre-

heated to 240°C. After standing for 5 min. at 240°C, a total force of 100 lbs. was applied to the assembly, which was then cooled to room temperature with maintenance of pressure. A well-formed lens was obtained; weight 138.3 mg; central thickness 0.42 mm.

65 The subsequently edged lens weighed 137.7 mg. The overall diameter was 13.5 mm and the diameter of the optic zone was 8 mm. The lens was made wettable as described in Example 1. The lens was placed on a patient. It provided visual acuity of 20/15 while the patient was also wearing a -1.00D auxiliary ophthalmic lens to correct for a slight difference between the power of the lens and the refractive requirement of the patient.

70 The poly(perfluoropropylene oxide)-plasticized TFE/P,MVE copolymer was prepared as follows. A quantity of TFE/P,MVE (64/36 mol ratio) copolymer was dissolved in dichlorooctafluorobutane and to the solution was added a quantity of poly(perfluoropropylene oxide) oil equal to 10% of the combined weight of polymer and plasticizer. The solution was filtered and the polymer recovered by evaporation of the solvent. The plasticized polymer was transparent, colorless, tough and elastomeric, and somewhat softer to the touch than unplasticized TFE/P,MVE. A 16-mil film was prepared by pressing a quantity of the plasticized polymer between 2 sheets of polyimide film at 260°C.

WHAT WE CLAIM IS:—

95 1. A wettable contact lens for the eye constructed from at least one fluorine containing polymer and having an optical zone designed to lie over the surface of the eye in a position to correct a vision defect, wherein the lens consists of at least one fluorine containing homopolymer, copolymer, or combination or blend of a polymer derived solely from fluoromonomers or from fluoromonomers with non-fluorinated monomers, and wherein the lens has a refractive index of 1.30 to 1.40, a Knoop hardness of less than 2 at loadings up to 25 grams, and a Shore Durometer "A" hardness of less than 100.

100 2. A contact lens according to claim 1 which is provided with a patterned posterior lens surface comprising channels substantially parallel to the surface of the eye and extending into the optical zone but not through the anterior surface of the lens.

105 3. A contact lens according to claim 1 or 2 wherein the fluorine containing polymer is tetrafluoroethylene / perfluoro(methyl vinyl ether) copolymer.

110 4. A contact lens according to claim 1 or 2 wherein the fluorine containing polymer is tetrafluoroethylene / perfluoro(methyl vinyl ether) copolymer plasticized with poly(hexafluoropropylene oxide) oil.

115 5. A contact lens according to claim 1 or 2 wherein the fluorine containing polymer is

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- hexafluoroacetone/ethylene oxide/propylene oxide copolymer.
6. A contact lens according to claim 1 or 2 wherein the fluorine containing polymer is polyfluorral.
7. A contact lens according to claim 1 or 2 wherein the fluorine containing polymer is hexafluoroacetone/vinylidene fluoride copolymer.
- 10 8. A contact lens according to claim 1 or 2 wherein the fluorine containing polymer is tetrafluoroethylene/perfluoro[2(2 - fluoro-
- sulfonyloethoxy)propyl vinyl ether] copolymer.
9. A contact lens according to claim 1 substantially as described herein in any one of 15 the foregoing Examples 1 to 17.
10. A contact lens according to claim 1 substantially as described herein with reference to any of Figures 1 to 18 of the drawings.

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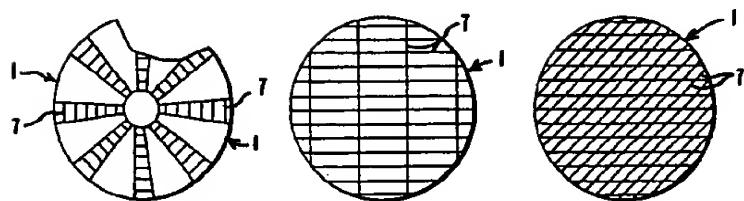
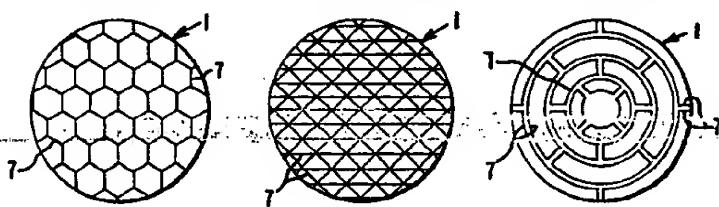
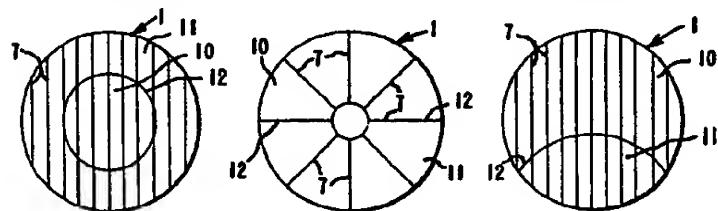
FIG.10 FIG.11 FIG.12**FIG.13 FIG.14 FIG.15****FIG.16 FIG.17 FIG.18**

FIG. 1

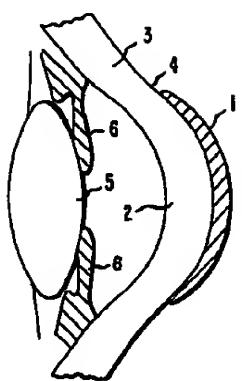


FIG. 2

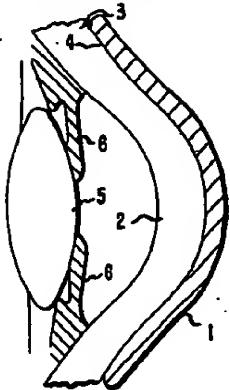


FIG. 3

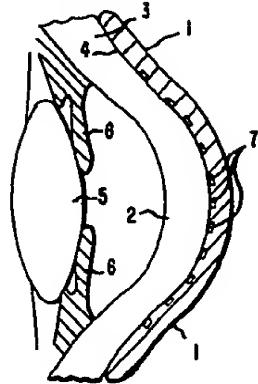


FIG. 4

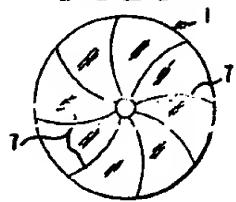


FIG. 5

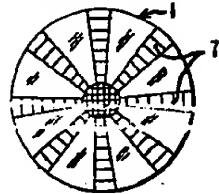


FIG. 6

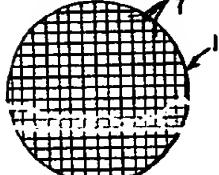


FIG. 7

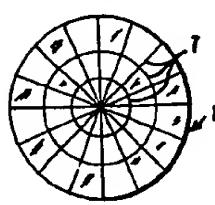


FIG. 8

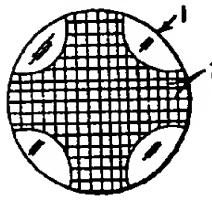


FIG. 9

